510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: k130275

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SEP 2 6 2013

Preparation Date:
May 29, 2012

Device Information:
Trade or Proprietary Name:
QuikScreen™ Multi (MDMA and OPI) Drug Cup Test Device
Common/Usual Name:
Lateral flow immunochromatographic assay for detection of MDMA and OPI in human urine

Device Classification Name:
Immunoassay of MDMA

Immunoassay of OPI

Regulatory Name:
MDMA Test System

OPI Test System

Regulation Section: 21 CFR § 862, 3650

21 CFR§ 862, 3610

Regulatory Class: Class II

Product Code: LAF, DJG,

Panel: Toxicology (91)

Substantially Equivalent devices:

QuikScreen™ Multi (MDMA and OPI) Drug Cup Test Device is substantially equivalent to predicate device (Guanzhou Wondfo Biotech Co Multi-Drug Urine Test Cup) cleared by FDA (K121166) for its stated intended use.

Product Description:

QuikScreen™ Multi (MDMA and OPI) Drug Cup Test Device is a convenient specimen collection cup with a built-in strip holder, which is able to hold the Strip of MDMA and OPI within the container. The membrane of the MDMA test strip is coated with goat anti-mouse antibody and MDMA-Bovine serum albumin conjugate. The membrane of the OPI test strip is coated with goat anti-mouse antibody and OPI-Bovine serum albumin conjugate. The sample pad of the MDMA test strip contains a colloidal gold-labeled mouse monoclonal anti-MDMA antibody. The sample pad of the OPI test strip contains a colloidal gold-labeled mouse monoclonal anti-OPI antibody. As the test sample flows through the absorbent device, the Colloidal Gold labeled antibody-conjugate binds to the free drug in the specimen forming an antibody-conjugate in the test reaction zone and will not produce a magenta color band when the drug is above the detection level of drug (500ng/ml of MDMA or 300ng/ml of OPI). Unbound colloidal gold-labeled antibody conjugate binds to the reagent in the control zone, producing a magenta color band, demonstrating that the reagents and device are functioning correctly. A color line will always appear at the control region. A negative specimen produces two distinct color bands in both the test line and control area. A positive specimen produces only one color band in the control area. There is no meaning attributed to color or its intensity for either line. The test is easy and fast allowing the user to read the screen for abuse of drugs without the need for any other instrumentation to determine results. The tester will obtain a result in five minutes. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly in evaluating a preliminary positive result. This test is the first step in determining whether there are drugs in the urine. If the test result shows 1 line (preliminary positive) you should send the sample for laboratory testing.
QuikScreen™ Multi (MDMA and OPI) Drug Cup Test is for diagnostic and treatment purposes, consult with a healthcare or substance abuse professional.

Intended Use:

The QuikScreenTM Multi (MDMA and OPI) Drug Cup Test consists of competitive binding , lateral flow immunochromatographic assays and provides a simple and rapid analytical screening procedure to simultaneously detect the drugs of abuse MDMA at or above the cutoff level of 500 ng/ml and OPI at or above the cutoff level of 300 ng/ml in human urine. The device is intended for OTC and prescription use..

Test	Calibrator	Cutoff
Opiate	Morphine	300 ng/ml
MDMA	(+/-)-3,4 Methylene-dioxymethamphetamine	500 ng/ml

The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method. Clinical and professional judgment should be exercised with any drug of abuse test result, particularly when preliminary results are used.
The assay does not distinguish whether OPI or MDMA is being taken therapeutically or abused.

Comparison to Predicate Device(s):
Tianjin New Bay QuikScreen™ OTC and CLIA WAIVED Multi (MDMA and OPI) Drug Cup Test is substantially equivalent to Guanzhou Wondfo Biotech Co Multi-Drug Urine Test Cup cleared by FDA (K121166).

Device Characteristics	**Subject Device (s) Tianjin New Bay QuikScreen™ Multi (MDMA and OPI) Drug Cup Test device.**	**Predicate Device(s)** Guanzhou Wondfo Biotech Co Multi-Drug Urine Test Cup cleared by FDA (K121166).	
Intended Use	QuikScreen™ Multi (MDMA and OPI) Drug Cup Test. The assay provides a simple and rapid analytical screening procedure to detect MDMA, and OPI, in human urine	Multi-Drug Urine Test are Immunochromatographic Qualitative Strip test. The assay provides a simple and rapid analytical screening procedure to detect MDMA ,OPI and other drug in human urine	Same
Analytes	MDMA, OPI	MDMA, OPI	Same
Technology	Using monoclonal /polyclonal antibody for the colloidal gold conjugate, Drug-BSA conjugate for the test line of the membrane	Using monoclonal /polyclonal antibody for the colloidal gold conjugate, Drug-BSA conjugate for the test line of the membrane	Same
Cutoff	MDMA: 500ng/ml, OPI: 300ng/ml	MDMA: 500ng/ml, OPI: 300ng/ml	Same
Assay time	5 minutes	5 minutes	Same
Preliminary Positive Reconfirm by GC/MS or LC/MS	Yes	Yes	Same
Matrix	Urine	Urine	Same
Calibrator	None	None	Same
Instrument	None, Visual read single use	None, Visual Read single use	Same
Calibration of Reagent	None	None	Same
Storage	Below 28°C until expiration	Below 28°C until expiration	Same

Performance Comparison	**MDMA** **Sensitivity**: ≥500 ng /ml of MDMA in urines show positive result OPI **Sensitivity**: ≥300 ng /ml of OPI in urines show positive result	**MDMA** **Sensitivity**: ≥500ng /ml of MDMA in urines show positive result OPI **Sensitivity**: ≥300 ng /ml of OPI in urines show positive result	**Same** **Same**
	Total Precision: The results demonstrate that there is no appreciable within and inter lot variation when testing both positive and negative spiked samples across three (3) different lots of test device at different day. The test result of both within lot and inter lot reproducibility are similar as Predicate device.	**Total Precision**: The results demonstrate that there is no appreciable within and inter lot variation when testing both positive and negative spiked samples across three (3) different lots of test device at different day	**Same**
	Cutoff determination: The cutoff is 500 ng/ml of MDMA. 50% below the cutoff level of MDMA are negative. The result set at cutoff and 25 % above cutoff level of MDMA are positive and similar to the predicate device. The cutoff is 300 ng/ml of OPI. 50% below the cutoff level of OPI are negative. The result set at cutoff and 25 % above cutoff level of OPI are positive and similar to the predicate device.	**Cutoff determination**: The cutoff is 500 ng/ml of MDMA. 50% below the cutoff level of MDMA are negative. The result set at cutoff and 25 % above cutoff level of MDMA are positive The cutoff is 300 ng/ml of OPI. 50% below the cutoff level of OPI are negative. The result set at cutoff and 25 % above cutoff level of OPI are positive	**Same**
	Accuracy: A comparison study of positive and negative specimens or lay user study with reference methods were performed, the test results	**Accuracy**: A comparison study of positive and negative specimens or lay user study with reference methods were performed, the test results was correlated	**Similar**

	was correlated very well with reference methods. It is similar as the predicate device	very well with reference methods.	

Summary:

The information provided in this pre-market notification demonstrates that QuikScreen™ Multi (MDMA and OPI) Drug Cup Test is substantially equivalent to Guanzhou Wondfo Biotech Co Multi-Drug Urine Test Cup cleared by FDA (K121166) for its stated intended use and GC/MS or LC/MS.

Substantial equivalence was demonstrated through comparison of intended use and physical properties to the commercially available and analytical predicate devices. The information supplied in this pre-market notification provides reasonable assurance that the QuikScreen™ Multi (MDMA and OPI) Drug Cup Test Device is safe and effective for its stated intended use.

Cross interference study by incorporation MDMA (500ng/ml cutoff), OPI (300ng/ml cutoff) Strip into the QuikScreen™ Multiple 11 drug cup device that had previously received clearance from the agency with the assigned 510(K) number as K071489. It was cleared for OTC test and Prescription Test. The cross interference study have indicated that there is no cross-interference between the strips and no effect on either positive or negative result among 13 different drug strip by the addition of the MDMA (500ng/ml as cutoff), OPI (300ng/ml as cutoff) test strip into the QuikScreen™ Multiple 11 drug Cup device .

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 26, 2013

Tianjin New Bay Bioresearch Co., Ltd.
c/o Roger de Bock
4455 Murphy Canyon Rd.
Suite 204
SAN DIEGO CA 92123

Re: K130275
Trade/Device Name: Quikscreen Multi (MDMA and OPI) Drug Cup Test
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: II
Product Code: DJG, LAF
Dated: August 21, 2013
Received: August 26, 2013

Dear Mr. de Bock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k130275

Device Name: QuikScreen™ Multi (MDMA and OPI) Drug Cup Test

Indications for Use:

The QuikScreen™ Multi (MDMA and OPI) Drug Cup Test consists of competitive binding , lateral flow immunochromatographic assays and provides a simple and rapid analytical screening procedure to simultaneously detect the drugs of abuse MDMA at or above the cutoff level of 500 ng/ml and OPI at or above the cutoff level of 300 ng/ml in human urine. The device is intended for prescription use and Over-The-Counter settings.

Test	Calibrator	Cutoff
Opiate	Morphine	300 ng/ml
MDMA	(+/-)-3,4Methylene-dioxymethamphetamine	500 ng/ml

The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method. Clinical and professional judgment should be exercised with any drug of abuse test result, particularly when preliminary results are used. The assay does not distinguish whether OPI or MDMA is being taken therapeutically or abused.

Prescription Use __X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use __X__. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S
2013.09.26 08:27:43 -04'00'
Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k130275